

REMARKS

Claims 26-48 are pending in the above-referenced application. As will be discussed in further detail below, claims 26, 29 and 34-39 have been amended to more distinctly claim that which Applicants regard as their invention. Claims 34-39 have been amended to change their dependencies. No new matter has been added.

1. The Rejections Under 35 U.S.C. 103

Claims 26-48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al., WO 99/19313 (hereinafter "Lohray"). Specifically, it is stated:

....Lohray teaches a process for the preparation of (-)3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid compounds, their pharmaceutically acceptable salts and pharmaceutical compounds containing them (see reference page 1, lines 1-22). The composition can be in the form of a tablet, capsule, powder, syrup, solution, or suspension (claim 19). The applicant's argument that Lohray does not teach a compression method is disagreed upon since Example 7 (A-C) clearly demonstrates a process for the preparation of the instant compound whereby a reaction mixture was obtained and formulated into a solid end product.

Further, the applicants argument that no suggestion was given regarding the advantages of a low water content is not persuasive since Lohray at page 31, line 15 clearly teaches the composition to be in suitable forms, such as tablets, capsules and powders. As such, these compressed solid forms would not contain significant amounts of water, if any. In addition, it would have been obvious to one of ordinary skill in the pharmaceutical art to determine suitable amounts of water or any other component for that matter, through routine or manipulative experimentation based on the purpose intended. Lohray explicitly teaches solid dosage forms (i.e. tablet, powder, etc.) whereby high amounts of water would be exempt.

The prior art teaches a similar process for preparing a composition, which comprises the same compound ((-)3-

[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid) as instantly claimed. Therefore the instant invention remains obvious and unpatentable over the prior art.

Applicants respectfully traverse the rejection. First, there was no suggestion in Lohray that it would be advantageous to obtain a composition having a low water content. Specifically, Lohray states on page 31, lines 14-20:

The pharmaceutical composition may be in the forms normally employed, such as tablets, capsules, powders, syrups, solutions, suspensions and the like, may contain flavourants, sweeteners etc. in suitable solid or liquid carriers or diluents, or in suitable sterile media to form injectable solutions or suspensions. Such compositions typically contain from 1 to 20 %, preferably 1 to 10 % by weight of active compound, the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents.

Clearly, no direction is given as to what would be optimal. Actually, it would appear that the composition could be in either solid or liquid form. No indication is given that it would be advantageous to obtain a composition having a low water content.

Furthermore, claim 26 has been amended to recite that the composition comprises anhydrous lactose, cellulose microcrystalline, talc and magnesium stearate as excipients and have a low water content. Applicants have submitted a Declaration Under 37 C.F.R. 1.132 showing that formulation by direct compression using microcrystalline cellulose, anhydrous lactose, talc and magnesium stearate as excipients is by far superior to either melt granulation using anyhydrous lactose, macrogol and talc as excipients or wet granulation using microcrystalline cellulose, lactose monohydrate, talc and magnesium stearate as excipients. These results were totally unexpected. Therefore, the claimed compositions would not obvious over the cited reference.

In view of the above arguments, Applicants assert that the rejection under 35 U.S.C. 103 have been overcome. Therefore, Applicants respectfully request that the rejection be withdrawn.

4. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact Cheryl H. Agris by telephone at (914) 712-0093 if there are any questions concerning this amendment or application.

Respectfully submitted,

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